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OFFICE OF THE CHIEF DISTRICT MEDICAL & PUBLIC HEALTH OFFICER, BARGARH

Notice No 2230 /CDM & PHO, Bargarh Dated 02.03.19

TENDER CALL NOTICE

Sealed tenders are invited from the willing supplier/wholesaler/manufacturers to quote the rates of **"iBreast Exam Machine".** The willing bidders are requested to submit their sealed tenders to the office of the undersigned by Speed Post/Regd. Post/Courier Service only on or before dt 12.03.19 till 4 P.M. The said tenders will be opened on dt. 12.03.19 at 5 pm ~~A.M~~. and after due date & time any tender will not be entertained. The bidders or their representatives are requested to remain present in the fixed date & time. The term & conditions and specification iBrest Exam Machine can be down loaded from the district website-www.bargarh.nic.in

The undersigned reserves the right to accept/cancel all the tenders without assigning any reason thereof.

Sd/- Dr. Nanda Kishore Padhi
Chief District Medical & Public Health Officer,
Bargarh

Memo No 2231 /CDM & PHO Bargarh Dated 02.03.19

Copy forwarded to the District Informatics Officer, NIC, Bargarh for information. He is requested to upload the details information & publish the same in the district website.

2/3/19
Chief District Medical & Public Health Officer
Bargarh

Memo No 2232 /CDM & PHO Bargarh Dated 02.03.19

Copy forwarded to DIPRO,Bargarh for favour of information and necessary action. She is requested to publish the above advertisement as mentioned on the table in one English New Paper & One Odiya News Paper for wide Publication.

2/3/19
Chief District Medical & Public Health Officer
Bargarh

Memo No 2233 /CDM & PHO Bargarh Dated 02.03.19

Copy submitted to the Collector & District Magistrate, Bargarh for information & necessary action.

2/3/19
Chief District Medical & Public Health Officer
Bargarh

Memo No 2234 /CDM & PHO Bargarh Dated 02.03.19

Copy to Notice Board for information & wide publication.

2/3/19
Chief District Medical & Public Health Officer
Bargarh

TERM & CONDITIONS:-

Copy of :-

1. Copy of GSTIN Certificate/PAN/TIN certificate, Authorization letter from manufacturer's & Copy of GMP/ISO certificate etc should be attached with the tender.

2..Processing fee Rs.2,000/-(non-refundable) in shape of demand draft should be submitted with the tender & the EMD money @.2% (refundable) in shape of demand draft issued from any Nationalized Bank will be submitted after receipt of purchase order on purchase value by the bidders with the bill/invoice in favor of CDM & PHO, Bargarh.

3.The goods should be supplied /delivered at District Ware House, Bargarh destination only and no charge for freight should be claimed.

4.The technical bid & financial bid should be submitted separately with the tender.

5.The rates should be quoted with GST tax.

6.The decision/selection of technical expert committee is final.

7.The quoted product/ items of photo copy should be submitted with the tender. .

8.Any tender will not be entertained after due date & time fixed for it.

9.Any postal delay, the undersigned will not be held responsible.

10.The bidders should be submitted all tender documents duly attested by Notary.

11.The approved rate will be valid for one year from the date of finalization of tender.

12. Once an order is placed, the firm/supplier has to be supplied the required items within a specific period i.e.30-45 days, failing which penalty will be levied/charged @. 0.5% on purchase value per week beyond specific period for 8 weeks ,which will be subject to maximum 4% & order can be cancelled if not supplied within the scheduled date & the concerned bidder will be black listed for next 3 (three) years from the date of issue of the letter and also the EMD money/Security deposit will be forfeited.

DETAILS OF THE BIDDERS & LOCAL CONTACT PERSON

Details.	Corporate office (The address in which the purchase order and payment details will be communicated)	Local Contract person/Branch Office/ Service Center if any, In Odisha
Name & Full Address		
Telephone Nos., Landline Nos.		
Mobile		
Fax		
E-Mail		
Name of Bank with A/C No and Name of Beneficiary		
IFSC Code		

Signature of the tenderer:
With Seal

SPECIFICATIONS FOR HAND HELD, POINT-OF-CARE BREAST HEALTH EXAMINATION SYSTEM FOR WOMEN STARTING AT AGE 30

1. **Point-of-Care device for breast examination (defined as "system") for documenting signs of lumps and lesions in the breast** having following key features:
    a. **The system should be entirely non-invasive**; meaning operates without passing any radiation, x-rays, gamma rays, sound waves, magnetic resonance, laser, optical light or any other signal through the human body.
    b. **The system should be entirely painless**; meaning operate without causing any discomfort or pain of any kind to the woman being examined
    c. **The system should be radiation-free**; meaning operate without making use of any ionizing radiation such as x-rays.
    d. **The system should be operable with rechargeable battery**with at least 10 hours of continuous usage without requiring to be plugged to the wall for recharging. The system should be fully re-charged within 5 hours for 10 hours of usage again.
    e. **The system should be operable wirelessly** using Bluetooth 2.0 or similar standard protocol
    f. **The system should be ultra-portable and having light-weight breast examination probe.** Probe size no larger than: 13 x 6.5 x 8.5cm, with max. Weight: 0.5kg.Full system with case size not exceeding: 27 x 26 x 11cm, max weight: 3kg.
    g. **The system should be operable by ASHA/ANM level Community Health Worker (CHW);** training time of one day to get certified in its use.
    h. **The system should provide instant results at the point-of-care without requiring an internet connection;** ASHA/ANM level CHW should be able to create a breast examination report covering all quadrants of the breast showing digital documentation of the breast exam
    i. **The system should provide a standardized report of the breast exam** both, in stored PDF and print format.

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2. **The system should have a minimum data storage capacity** for 30,000 breast examination scans and full reports locally in the computing system that's part of the system.

3. **The system should have the ability to transfer the data remotely to a cloud server** via wireless internet connectivity

4. **The system should enable ASHA/ANM level CHW to perform a bilateral breast examination in less than 10 minutes.**

5. **The system must have a software interface to perform breast examinations with capabilities to:**
    a. Perform breast examination
    b. Review the breast examination
    c. Store the breast examination data
    d. Store Manual Clinical Breast Examination data
    e. Document data on follow-on test results
    f. Print the final report

6. **The system must have the ability to check the quality and performance of the ASHA/ANM CHWs performance** by enabling the reviewer/trainer/doctor/specialist to replay a breast examination performed in the past, frame by frame, remotely.

7. **The system should be US FDA cleared and CE marked as a Class 1 device; the Indications for Use must be defined as "breast lesion documentation system".** The US FDA and CE mark registration for such purpose should be active and in good standing, without any reported adverse events, complaints or warnings for the product by the US FDA or CE mark in the

last five years. The FDA and CE mark approval for such purpose should not be more than 5 years ago.

8. **The system should have an independent, third party, Health Technology Assessment report** based on the World Health Organization standards, created within the last 36 months

9. **The system should be tested and approved for Electromagnetic Compatibility (EMC)Test based on these standards:**
   a. 1409-054EA REV. A TEST STANDARDS: IEC 60601-1-2:2007 (3RD EDITION) and
   b. IEC 60601-1-2:2014 (4TH EDITION)

10. **The system should be approved for the following Electrical and Mechanical Safety Tests based on these standards:**
    a. IEC 60601-1 Ed.3 (2005) + Am.1 (2012) = IEC 60601-1 Ed.3.1 (2012)
    b. The following National Deviations were included in the evaluation: - AAMI/ANSI ES 60601-1:2005(R) 2012/A1
    c. EN 60601-1 Ed.3 (2007) + Am.1 (2013)
    d. CSA C22.2 No. 60601-1:2014

11. **The system should have been clinically validated in Indian women population** of minimum 1,000 individuals.

12. **The system should have published clinical validation performance characteristics with:**
    a. Minimum Sensitivity of 80% to detect clinically relevant breast lesions
    b. Minimum Specificity of 90%
    c. Minimum Negative Predictive Value of 95%
    d. Minimum Positive Predictive Value of 60%

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13. **The system should be Storable, Transportable and Operable in the following environmental conditions:**
    a. Temperature range: -10C to40C
    b. Maximum relative humidity: 90%
    c. Atmospheric pressure range: 700- 1060 hPa

14. **The system should have at least 3 references/Key Opinion Leader support letters** and should have been used in at least 10,000 Indian women

15. **The provider should have support from a nationally recognized governmental agency for implementation monitoring & evaluation**

16. **The Company should be ISO 13485 and WHO-GMP certified with internal quality management systems and controls**